

**UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA**

**THE CITY OF HUNTINGTON,
Plaintiff,**

v.

CIVIL ACTION NO. 3:17-01362

**AMERISOURCEBERGEN DRUG
CORPORATION, et al.,
Defendants.**

**CABELL COUNTY COMMISSION,
Plaintiff,**

v.

CIVIL ACTION NO. 3:17-01665

**AMERISOURCEBERGEN DRUG
CORPORATION, et al.,
Defendants.**

**PLAINTIFFS' REPLY MEMORANDUM IN SUPPORT OF MOTION
TO ADOPT MULTIDISTRICT LITIGATION COURT'S ORDER ON
DEFENDANTS' CONTROLLED SUBSTANCES ACT DUTIES**

Plaintiffs The City of Huntington and Cabell County Commission (collectively, "Plaintiffs") submit this reply memorandum in further support of their motion (ECF Doc. 189) for the Court to adopt the August 19, 2019 ruling of the multidistrict litigation court – the U.S. District Court for the Northern District of Ohio, Hon. Dan A. Polster, U.S.D.J. (the "MDL Court") -- with regard to Defendants' duties under the federal Controlled Substances Act 21 U.S.C. §§ 801 *et seq.*, ("CSA"), in these remanded actions. Plaintiffs state in reply to Defendants' opposition to their motion as follows.

INTRODUCTION

Plaintiffs moved this Court to adopt the MDL Court's August 2019 order granting partial summary judgment and setting forth Defendants' duties under the federal CSA (the "CSA ruling") because there are no changed or exceptional circumstances that would justify eschewing that ruling here. Absent such circumstances, the MDL Court's ruling should be accorded deference on remand as presumptively correct. In their opposition, Defendants ignore statutory purpose and prudential concerns to argue that the MDL Court's rulings should be given no deference whatsoever and that this Court should re-examine every previously addressed issue *de novo* because this is a separate case involving different Plaintiffs. *See* Defendants' Memorandum of Law in Opposition (ECF Doc. 235) ("Opp.") at 2-12. The Court should reject this argument.

Defendants' effort to revisit every one of the MDL Court's rulings would undermine the very structure and purpose of multidistrict litigation. Federal law provides for consolidation and transfer of actions involving common questions of law and fact to "promote the just and efficient conduct of such actions." 28 U.S.C. § 1407(a). This means that common issues are to be decided in a streamlined and consistent manner as to all similarly situated parties. As one leading authority explains, the "very purpose of the initial consolidation is to resolve common matters consistently *across the consolidated cases*." 18B Charles Alan Wright & Arthur R. Miller, *Federal Practice and Procedure* (2d ed. 1987), § 4478.4 (Law of the Case-Coordinate Courts) (emphasis added). Courts do this by applying law of the case

principles, *see* Manual for Complex Litigation, Fourth (“MCL 4th”), § 20.133 at 226, which assure efficient and consistent resolution of common questions, while also affording remand courts the flexibility to address truly changed or extraordinary circumstances. *Cf. Royster v. Food Lion, Inc.*, 73 F.3d 528, 532 (4th Cir. 1996) (“If transferor judges were permitted to upset rulings of transferee judges, the result would be an undermining of the purposes and usefulness of transfer under Section 1407 for coordinated or consolidated pretrial proceedings”) (quoting Hon. Stanley A. Weigel, *The Judicial Panel on Multidistrict Litigation, Transferor Courts and Transferee Courts*, 78 F.R.D. 575, 577 (1978)).

Here, Defendants identify no changed or extraordinary circumstance that would warrant reconsideration of the MDL Court’s CSA ruling. They instead contend that the ruling is clearly erroneous and that its adoption would cause manifest injustice primarily because it answered allegedly “abstract” questions of duty under the CSA with no connection to any party’s claims. *See* Opp. at 13-15. This is incorrect. Judge Polster decided these questions regarding the contours of ***these*** Defendants’ duties as they related to the same type of public nuisance claim in a different jurisdiction in the bellwether Track One (“CT1”) cases. As the term “bellwether” indicates, this was not an abstract exercise, but rather one addressing a set of circumstances that was meant to advance and inform both those cases and the entire litigation.

The questions answered by Judge Polster as to what federal legal duties these Defendants are subject to under the CSA likewise are material to Plaintiffs’

common law public nuisance claims here. *See* Third Amended Complaint (“3AC”), ¶¶ 1403, 1421-22; *see also Pope v. Edward M. Rude Carrier Corp.*, 75 S.E.2d 584, 589 (W. Va. 1953) (“In legal phraseology the term ‘nuisance’ is applied to that class of wrongs which arises from the unreasonable, unwarrantable *or unlawful* use by a person of his own property and produces such material annoyance, inconvenience, discomfort, or hurt that the law will presume a consequent damage.”) (quoting 39 Am. Jur., Nuisances, § 2) (emphasis added). Plaintiffs’ motion and the MDL Court’s CSA ruling thus address a matter that is in controversy between the parties.

Defendants’ only other argument is that the MDL Court clearly erred by misconstruing the CSA with respect to the duties to identify, report, and stop shipment of suspicious orders that are at issue. *See* Opp. at 15-20. This attempt to re-argue the CSA issue wholesale illustrates precisely why law of the case and prudential considerations require that *before* courts such as this one are called upon to revisit every past ruling of a transferee court, Defendants must demonstrate changed or other extraordinary circumstances.

But even if this Court did deem it appropriate to re-examine Judge Polster’s well-reasoned opinion, it would find that he did not err, either clearly or otherwise. Judge Polster found existing federal case law persuasive in construing and applying the CSA to impose these duties upon Defendants in order to prevent diversion of controlled substances, and not merely (as Defendants argued there and again here) as a formal Drug Enforcement Agency (“DEA”) registration requirement. *See* CSA Order at 14-15; *see also* 21 U.S.C. § 821 (authorizing regulations “relating to the

registration *and control* of the . . . distribution . . . of controlled substances”) (emphasis added); 21 C.F.R. § 1301.74(b) (duties to identify and report suspicious orders); *Masters Pharm., Inc. v. DEA*, 861 F.3d 206, 212 (D.C. Cir. 2017) (“Once a distributor has reported a suspicious order, it must make one of two choices: decline to ship the order, or conduct some ‘due diligence’ and—if it is able to determine that the order is not likely to be diverted into illegal channels—ship the order . . .”).

Since the MDL Court’s CSA ruling is to be accorded deference on remand as presumptively correct, and was correctly decided in all its particulars in any event, this Court should adopt the CSA ruling as establishing Defendants’ duties to prevent diversion of controlled substances in these cases.

ARGUMENT

A. The MDL Court’s CSA Ruling Should Be Accorded Deference on Remand as Presumptively Correct, Subject to Law of the Case Principles.

Defendants’ primary argument in opposition is that the MDL Court’s CSA ruling should be accorded no deference whatsoever and that this Court must decide identical issues presented here (and in any other motion) *de novo* because the law of the case doctrine only applies within a single case, with no exception for consolidated cases. *See Opp.* at 2-3. The Court should reject this argument that the consolidation and transfers of these actions are irrelevant in addressing previously-decided issues within the MDL.

The MDL statute states that its purpose in authorizing consolidation and transfer of actions raising common issues is to “promote the just and efficient

conduct of such actions.” 28 U.S.C. § 1407(a). There is nothing efficient or just in Defendants’ proposed system of having common or identical issues like the one presented here be decided *de novo* time and again in every individual case in which the issue arises.

This is precisely why authorities instruct that rulings of MDL courts on common issues deserve special respect or deference after remand not only within each consolidated case, but also *between* consolidated cases. Wright and Miller, *supra*, states squarely that “the very purpose of the initial consolidation is to resolve common matters consistently *across the consolidated cases*[.]” so that “[f]ollowing remand to a court of original filing, rulings in the consolidated proceedings deserve special respect in keeping with the purposes of consolidation” and “there should be a very strong pressure to carry the [consolidation court’s] view *with each case* as it may be remanded to the originating court,” even if the originating court has doubts about its correctness. Wright and Miller, *supra*, § 4478.4 (emphasis added).

The Manual for Complex Litigation similarly instructs remand courts that they should effectuate the MDL consolidation statute’s purpose to promote just and efficient resolution by applying law of the case principles in addressing issues previously decided by an MDL court. The MCL specifies that, although a transferor court like this one *may* vacate or modify rulings made by an MDL court after remand, this power is “subject to comity and ‘law of the case’ considerations” and that “doing so in the absence of a significant change of circumstances would frustrate the purposes of centralized proceedings.” MCL 4th, § 20.133 at 226; *see*

also Royster, 73 F.3d at 531 (“If transferor judges were permitted to upset rulings of transferee judges, the result would be an undermining of the purposes and usefulness of transfer under Section 1407 for coordinated or consolidated pretrial proceedings”) (quoting Weigel, *supra*, 78 F.R.D. at 577).

Defendants dispute that the MCL and the Fourth Circuit’s approach in *Royster* cited above could ever apply across separate consolidated cases. *See Opp.* at 7 (“That [MCL] passage plainly does not say that orders entered by the MDL court in one case are law of the case in different cases.”). This assertion, however, ignores the MCL’s reliance upon the “purposes of centralized proceedings,” *i.e.*, to promote the just and efficient conduct of actions raising common questions, which clearly extend beyond rulings made within a single case. If every common issue had to be decided *de novo* in every separately-filed case, as Defendants urge, the statutory purposes of promoting just and efficient resolution would be defeated.

Although Defendants ignore these statutory purposes, their primary answer to them appears to be that those purposes are subordinate to some purported Article III or due process right Defendants’ claim to have that each court within which a case was filed make a *de novo* determination on every common or identical issue. *See Opp.* at 5 (“These clear limitations on the law of the case doctrine are rooted in the responsibility of Article III courts to develop the law and ensure due process by adjudicating the claims and defenses of the parties before them.”). No such “right” exists. This unmoored “due process” right to *de novo* determinations of every issue presented in every case would call into question not just law of the case

principles, but also such doctrines as non-mutual collateral estoppel, *stare decisis*, and general respect for precedent that courts routinely apply to ensure fair treatment of similarly situated litigants and prevent needless duplication of proceedings.

In any event, Defendants do not and cannot explain how their alleged right to an independent judicial determination of their defenses to Plaintiffs' motion could be violated here *when the MDL Court provided exactly this in cases where they were litigating parties*. See CSA Ruling at 13 (considering and rejecting argument raised by Defendants again herein that CSA duties only relate to DEA registration, not to preventing diversion). Defendants had a full and fair opportunity to be heard before Judge Polster. They are not entitled to the repeated bites at the apple they now seek.

Nor does the only case law Defendants cite for this argument, *see* Opp. at 5-6 (discussing *In re Korean Airlines Disaster*, 829 F.2d 1171 (D.C. Cir. 1987)), actually support it. In *Korean Air*, the court addressed an MDL transferee court's ruling on a federal law question on which the circuit courts of appeal for the transferor court and transferee court were in tension. *See* 829 F.2d at 1174. The court held that "the transferee court should be free to decide a federal claim in the manner it views as correct without deferring to the interpretation of the transferor circuit," *id.* at 1174 (internal quotation marks and citation omitted), and that once it did, when the cases returned to the transferor courts, the transferee court's ruling would have "binding force . . . as 'law of the case,' for if it did not, transfers under 28 U.S.C. §

1407 could be counterproductive, *i.e.*, capable of generating rather than reducing the duplication and protraction Congress sought to check.” *Id.* at 1176. *This is precisely the argument Plaintiffs make here.* Although Defendants are correct that *Korean Air* addressed potential remand of the same cases in which the ruling at issue had been made, its reasoning supports applying law of the case principles to common or identical issues across consolidated cases because the same concern under § 1407 for preventing “duplication and protraction” still applies.

Defendants also cite several cases that they claim “explicitly recognized that rulings by an MDL court in one case in an MDL are not binding law of the case in other cases in that MDL.” *Opp.* at 5. The cases Defendants cite, however, are not controlling and do not all even address the proposition for which Defendants cite them. In *In re Lipitor Antitrust Litig.*, 868 F.3d 231 (3d Cir. 2017), for example, the separate case to which the court referred in rejecting application of the law of the case doctrine was not part of the MDL at issue, but rather had been decided ten years prior to the MDL’s formation. *See id.* at 267-68 and n.18 (discussing district court’s reliance on ruling in 2002 lawsuit); *id.* at 245 (discussing *In re Lipitor Antitrust Litig.*, 856 F. Supp. 1355 (J.P.M.L. 2012)). This decision thus does not address or reject application of law of the case principles within an MDL.

Nor does *In re Interest Rate Swaps Antitrust Litig.*, 351 F. Supp. 3d 698 (S.D.N.Y. 2018), *see Opp.* at 5, which is an MDL *transferee* court decision declining to hold that *its own* earlier decisions compelled a result in a later case involving substantively different complaint allegations. *See id.* at 703 (“[E]ven if law of the

case doctrine applied here, that doctrine is flexible. The Court may deviate where there are cogent or compelling reasons for doing so. Here, such reasons are apparent.”) (internal quotation marks and citations omitted); *id.* at 704 (“With trueEX now seeking monetary relief and over a somewhat longer time period than implicated by the earlier complaints, fairness entitles defendants, faced for the first time with a claim for damages by trueEX, to contest the adequacy of its complaint on the merits.”).

This Court also should reject Defendants’ argument that it is “especially inappropriate” to apply law of the case principles on pure questions of law like the CSA questions here. *See* Opp. at 9. This Court long has recognized just the opposite—that the law of the case doctrine applies to questions of law and fact alike. *See, e.g., State of West Virginia v. Moore*, 897 F. Supp. 276, 280 (S.D. W. Va. 1995) (“[T]he Court’s decision is supported, though not required, by ‘law of the case’ doctrine. According to that doctrine, ‘where there is an unreversed decision of a question of law or fact during the course of litigation, such decision settles that question for all subsequent stages of the suit.’”) (quoting *Wilson v. Ohio River Co.*, 236 F. Supp. 96, 98 (S.D. W. Va. 1964)). There is thus no bar to applying law of the case principles to the purely legal CSA questions here.

So, too, should the Court reject Defendants’ argument that the MDL Court’s CSA ruling would not be subject to law of the case principles even in the CT1 bellwether cases where it was issued because it is interlocutory and not part of a final judgment. *See* Opp. at 10-11. The Fourth Circuit has held repeatedly that law

of the case principles apply to interlocutory rulings. *See, e.g., Carlson v. Boston Sci. Corp.*, 856 F.3d 320, 325 (4th Cir. 2017) (“[C]ourts have cabined revision pursuant to [Fed. R. Civ. P.] 54(b) by treating interlocutory rulings as law of the case.”); *id.* (“[A] court may revise an interlocutory order under the same circumstances in which it may depart from law of the case: (1) a subsequent trial producing substantially different evidence; (2) a change in applicable law; or (3) clear error causing manifest injustice.”) (internal quotation marks and citation omitted); *see also U.S. Tobacco Coop., Inc. v. Big South Wholesale of Va., LLC*, 899 F.3d 236, 257 (4th Cir. 2018) (same) (quoting *Carlson*).

These are precisely the law of the case principles or criteria that should govern this Court’s adoption of the MDL Court’s CSA Order. Defendants’ arguments for *de novo* determinations by this Court (and every remand court) of every common or identical issue decided by Judge Polster would defeat 28 U.S.C. § 1407(a)’s express objectives in providing for consolidation and transfer of actions raising common issues so as to “promote the just and efficient conduct of such actions.” For all of the reasons set forth, the Court should reject Defendants’ arguments and should apply law of the case principles in adopting the CSA ruling.

B. The Court Should Adopt the MDL Court’s CSA Ruling.

Defendants identify no changed or extraordinary circumstances that would warrant reconsideration of the CSA ruling consistent with law of the case principles. *See generally* MCL 4th, § 20.133 at 226 (vacating transferee court ruling “in the absence of a significant change of circumstances would frustrate the

purposes of centralized proceedings.”); *Carlson, supra*, 856 F.3d at 325 (“[A] court may revise an interlocutory order under the same circumstances in which it may depart from law of the case: (1) a subsequent trial producing substantially different evidence; (2) a change in applicable law; or (3) clear error causing manifest injustice.”) (internal quotation marks and citation omitted).

Defendants argue first that the CSA ruling was clearly or otherwise erroneous because its determination of purportedly “abstract ‘duties’ apart from the source of any law that would support the plaintiffs’ claim to relief in that case was inappropriate.” Opp. at 13-14. This fundamentally mischaracterizes the MDL Court’s ruling.

Judge Polster addressed the CT1 Plaintiffs’ “Motion for Partial Summary Adjudication of Defendants’ duties Under the Controlled Substances Act.” CSA Ruling at 1 (addressing MDL ECF Doc. 1887). The CT1 Plaintiffs permissibly sought this relief. *See* Fed. R. Civ. P. 56(a) (“A party may move for summary judgment, identifying each claim or defense – *or the part of each claim or defense* – on which summary judgment is sought.”) (emphasis added). The CT1 Plaintiffs identified their federal and state statutory and state law public nuisance claims to which the CSA duties were relevant. *See* MDL ECF Doc. 1887-1 (CT1 Plaintiffs’ Memo of Law). Judge Polster, moreover, recognized that a matter is “material” under Rule 56 “only if its resolution will affect the outcome of the lawsuit.” CSA Ruling at 2. The CSA ruling thus was material to the claims before that Court.

So, too, is the CSA ruling material to the CT2 Plaintiffs' public nuisance claim under West Virginia law here. Plaintiffs allege in support of this claim that "Defendants repeatedly engaged in *unlawful* and wrongful conduct which unreasonably interfered with and had a substantial impact upon the public health, giving rise to the opioid epidemic." 3AC, ¶ 1403 (emphasis added). Well-established West Virginia law supports a common law public nuisance claim based upon a defendant's allegedly unlawful conduct. *See, e.g., Pope, supra*, 75 S.E.2d at 589 ("In legal phraseology the term 'nuisance' is applied to that class of wrongs which arises from the unreasonable, unwarrantable *or unlawful* use by a person of his own property and produces such material annoyance, inconvenience, discomfort, or hurt that the law will presume a consequent damage.") (quoting 39 Am. Jur., Nuisances, § 2) (emphasis added). There is thus no serious question but that Judge Polster's CSA ruling was and is material both to the CT1 Plaintiffs' public nuisance claim under Ohio law that was before him and to the CT2 Plaintiffs' public nuisance claim under West Virginia law that is before this Court.¹

¹ Recognizing the CSA ruling's materiality to Plaintiffs' claims, Defendants make a passing argument that "[a]n attempt to create state law liability based on the federal CSA in these circumstances would raise serious questions of preemption by federal law" because "private enforcement of the CSA through state law tort claims would frustrate Congress' intent and contravene its judgments about how the CSA should be enforced." Opp. at 15. No it would not. Rather than interfere with the CSA, Plaintiffs' claims are of the type specifically *contemplated* by it. The CSA welcomes the states' traditional enforcement of tort law to supplement the federal enforcement scheme. *See* 21 U.S.C. § 903 ("No provision of this subchapter shall be construed as indicating an intent on the part of the Congress to occupy the field in which that provision operates, including criminal penalties, to the exclusion of any State law on the same subject matter which would otherwise be within the authority of the State, unless there is a positive conflict between the provision of

Defendants thus primarily argue that this Court should reconsider or reject the CSA ruling because it was clearly or otherwise erroneous as “contrary to the plain text of the federal CSA and regulatory provisions.” Opp. at 13. Defendants contend that Judge Polster erred in holding that the CSA provisions at issue create duties with respect to preventing diversion of controlled substances because these provisions only address their and other distribution companies’ requirements for “maintaining registration” with the DEA. Opp. at 17.

Judge Polster squarely addressed and correctly rejected this exact argument made by the same Defendants. *See* CSA Ruling at 14 (“Defendants assert the Reporting Requirement arises only in the context of factors that the DEA may consider in the registration process and creates no ‘legal duties’ *that would trigger liability to plaintiffs.*”) (emphasis in original). He rejected this argument as contrary to the CSA itself, which authorizes the DEA through the Attorney General to “promulgate rules and regulations . . . relating to the registration *and control of* the manufacture, distribution, and dispensing of controlled substances and to listed chemicals.” 21 U.S.C. § 821 (emphasis added).

Judge Polster also correctly recognized that the DEA regulations promulgated pursuant to the CSA did in fact impose duties related not only to a distributor’s registration, but also to its maintenance of controls to prevent

this subchapter and that State law so that the two cannot consistently stand together.”). The MDL Court previously rejected this argument, *see* MDL ECF Doc. 2565 at 22, and this Court should too, based upon the same law of the case principles set forth herein and in Plaintiffs’ other moving papers.

diversion. *See* CSA Ruling at 15 (citing 21 C.F.R. § 1301.74); *see also* 21 C.F.R. § 1301.74(b) (“The registrant shall design and operate a system to disclose to the registration the suspicious orders of controlled substances. The registrant shall inform the Field Division Office of the Administration in his area of suspicious orders when discovered by the registrant.”). He referred to these duties to identify and report suspicious orders as the “Reporting Requirement,” CSA Ruling at 14, and found that, “as a matter of law, Section 1301.74 imposes a legal duty on registrants to: (1) design and operate a system to disclose to the registrant suspicious orders; and (2) inform the DEA of suspicious orders when discovered by the registrant.” *Id.* at 15 (citing § 1301.74 and *Masters, supra*, 861 F.3d at 212). Since these rulings are not clearly or in any other way erroneous, the Court should adopt them consistent with law of the case principles.

So, too, did the MDL Court correctly hold that the CSA creates a duty not to ship suspicious orders that have not been resolved (the “No-Shipping Requirement”). *See* CSA Ruling at 15. Defendants contend that Judge Polster “rewrote the CSA to create a no-shipping requirement that does not appear anywhere in the text of the CSA or regulations.” *Opp.* at 17. Here, again, Defendants mischaracterize the CSA ruling and the well-established law on which it was based. Judge Polster relied upon 21 C.F.R. § 1301.71, which requires Defendants and other registered distributors to “provide effective controls and procedures to guard against theft and diversion of controlled substances.” 21 C.F.R. § 1301.71(a). He then construed this requirement in accordance with DEA

adjudicative decisions as addressed by the U.S. Court of Appeals for the D.C. Circuit in *Masters, supra*. See CSA Ruling at 17. In *Masters*, the D.C. Circuit held with respect to § 1301.71(a)'s requirement to maintain "effective controls" against "diversion," as construed and applied by the DEA itself, that "[o]nce a distributor has reported a suspicious order, it must make one of two choices: decline to ship the order, or conduct some 'due diligence' and—if it is able to determine that the order is not likely to be diverted into legal channels—ship the order (the Shipping requirement)." 861 F.3d at 212-13 (citing *Southwood Pharm., Inc.*, 72 Fed. Reg. 36,487, 36,500 (DEA July 3, 2007)).² Judge Polster thus followed well-established judicial and regulatory authority, and Defendants identify no authority whatsoever rejecting these judicial and agency interpretations of the CSA regulations at issue.

Since the MDL Court did not clearly or otherwise err in holding that the federal CSA and DEA regulations establish the "Reporting and Shipping Requirements" at issue in relation to Plaintiffs' common law public nuisance claims herein, this Court should adopt the CSA ruling consistent with applicable law of the case principles.

CONCLUSION

For all of the reasons set forth, the Court should grant Plaintiffs' motion and adopt the MDL Court's August 19, 2019 CSA Ruling.

² Although the D.C. Circuit referred to this as the "Shipping Requirement," Judge Polster's use of the term "No-Shipping Requirement" more accurately describes the nature of the duty at issue.

Dated: March 24, 2020

Respectfully submitted,

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CERTIFICATE OF SERVICE

I, Anthony J. Majestro, hereby certify that on March 24, 2020, I served the foregoing on all counsel of record using the CM/ECF system.

s/Anthony J. Majestro
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